Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 26, 2021 March 17, 2021, February 1, 2022, April 22, 2022

VILTEPSO™ (viltolarsen)

LENGTH OF AUTHORIZATION: SIX MONTHS

REVIEW CRITERIA:

- Patient must have the diagnosis of Duchenne Muscular Dystrophy (DMD).
- Submission of medical records (e.g., chart notes, laboratory values) as genetic test is required to confirm that a patient's mutation of the DMD gene is amenable to exon 53 skipping.
- Medication is prescribed by or in consultation with a neurologist or a physician who specializes in treatment of DMD (e.g., pediatric neurologist, cardiologist, or pulmonary specialist).
- Baseline testing prior to administration including serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio.
- Patient has been on stable dose of oral corticosteroids for at least 24 weeks prior to starting therapy unless contraindicated or intolerant.
- Patient is not concurrently treated with other DMD antisense oligonucleotides (e.g. golodirsen, casimersen, or eteplirsen).
- If the patient is ambulatory, functional level determination of baseline assessment of ambulatory function (six-minute walk test (6MWT), time to run/walk 10-meter test (TTRW), time to climb 4-stair test (TTCLIMB), time to stand (TTSTAND) or North Star Ambulatory Assessment (NSAA)) is required.
- If not ambulatory, patient must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improvement, maintenance or slowing of disease progression:
    - For ambulatory patients – submission of 6MWT, TTRW, TTCLIMB, TTSTAND or NSAA.
    - For non-ambulatory patients – submission of Brooke Upper Extremity Function Scale (five or less) documented OR a Forced Vital Capacity document (30% or more)
- Patient must be monitored for kidney toxicity.
- Patient is not concurrently treated with other DMD antisense oligonucleotides (e.g. golodirsen, casimersen, or eteplirsen).

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 250 mg/5 mL (50 mg/mL) single-dose vial